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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,186	07/08/2003	Arminas Ragauskas	01950-P0006D RJB	6458
24126	7590	12/14/2005	EXAMINER	
ST. ONGE STEWARD JOHNSTON & REENS, LLC 986 BEDFORD STREET STAMFORD, CT 06905-5619			APANIUS, MICHAEL	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 12/14/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/615,186

Applicant(s)

RAGASKAS, ARMINAS

Examiner

Michael Apanius

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13-18 is/are allowed.
- 6) ☒ Claim(s) 1-12 and 19-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11062003
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because some of the text is indiscernible (for example, the subscripts in figure 1) and reference numerals (figures 2A, 2C, 3A, 3B) and labels (figure 2B) are "hand-drawn". Furthermore, each of figures 1a, 1b, and 1c require a complete label next to each figure (i.e. --FIG. 1A--, --FIG. 1B--, etc.).
2. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Specification***

3. The disclosure is objected to because of the following informalities:
  - a. The title should read --Method and apparatus for a noninvasive determination of the absolute value of intracranial pressure--.
  - b. At paragraph 34, line 3, "cerebroventricies" should be --cerebroventricles--.
  - c. At paragraph 41, line 1, the meaning of "It is possible to achieve ICP=0 by applying a body tilting its head up" is not clear.
  - d. At paragraph 44, line 5, "of" should be deleted.
  - e. At paragraph 45, lines 1-2, the meaning of "A condition where ICP=0 is created by applying a body tilting its head up" is not clear.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 19-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. At claim 19, line 3, "a first position of a physiological object" is recited. At lines 6-7, "the position of the object is restored to its first position" is recited. It is unclear how the object changed from the first position so that it could subsequently be restored to

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that first position. Furthermore, it is unclear when an intracranial pressure is balanced with atmospheric pressure. For example, this could mean that intracranial pressure is equal to atmospheric pressure or it could mean that the force counteracting the intracranial pressure is atmospheric pressure.

7. Claims 19-24 are further rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: relating the value of the applied force to a measurement of the absolute pressure inside the cranium. This step is necessary to link the outcome of the method, obtaining a measurement of absolute pressure inside the cranium, to the value of the applied force.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Yost et al. (US 5,617,873).

10. In regards to claim 1, Yost et al. disclose a device (figure 2) for obtaining an indication of the intracranial pressure of a living body, comprising: a positional sensor (20) which is capable of determining an initial position of an elastic biological object when the intracranial pressure within the living body is zero and which is capable of

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determining a subsequent position of the elastic biological object when the intracranial pressure within the living body is unknown but greater than zero; a pressure generator (40) which applies an external pressure to the elastic biological object; and a comparator (30; column 6, line 22) which is capable of comparing the initial position with the subsequent position so as to identify the unknown intracranial pressure of the living body as that external pressure which causes the subsequent position to be equal to the initial position. Note that the positional sensor is an ultrasonic transducer which can be used to measure positions (column 6, lines 21-24).

11. In regards to claim 7, the device has a pressure indicator (60) for sensing the pressure applied by the pressure generator and indicating the pressure. The other elements of this claim are noted above in regards to claim 1.

12. In regards to claims 2 and 8, the elastic biological object is a skull bone (column 6, line 23).

13. In regards to claims 3 and 9, the pressure generator is an inflatable helmet (column 6, line 6).

14. Claims 1, 5-7, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchbanks (US 4,841,986).

15. In regards to claim 1, Yost et al. disclose a device (figure 3) for obtaining an indication of the intracranial pressure of a living body, comprising: a positional sensor (31; column 4, lines 51-58) which is capable of determining an initial position of an elastic biological object when the intracranial pressure within the living body is zero and

which is capable of determining a subsequent position of the elastic biological object when the intracranial pressure within the living body is unknown but greater than zero; a pressure generator (20) which applies an external pressure to the elastic biological object; and a comparator (34) which is capable of comparing the initial position with the subsequent position so as to identify the unknown intracranial pressure of the living body as that external pressure which causes the subsequent position to be equal to the initial position.

16. In regards to claim 7, the device is deemed to have a pressure indicator for sensing the pressure applied by the pressure generator and indicating the pressure. The pressure indicator is deemed necessary because the value of the applied pressure is needed to calculate middle ear pressure (column 5, lines 10-14). The other elements of this claim are noted above in regards to claim 1.

17. In regards to claims 5 and 11, the elastic biological object is a tympanic membrane (17).

18. In regards to claims 6 and 12, the pressure generator is a tube (20) adapted for insertion into an ear.

### ***Claim Rejections - 35 USC § 103***

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yost et al. (US 5,617,873) in view of Alban (US 4,505,278).

21. Yost et al. do not expressly disclose a piston and cylinder assembly mounted on a frame.

22. Alban teaches a piston (11B) and cylinder (10) assembly mounted on a frame (17) for the purpose of providing an inexpensive and accurate pressure generator (column 1, lines 39-43). The piston and cylinder taught by Alban is capable of applying pressure to a skull bone.

23. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a piston and cylinder assembly as taught by Alban in the device of Yost et al. in order to provide an inexpensive and accurate pressure generator.

***Allowable Subject Matter***

24. Claims 13-18 are allowed.

25. Claims 19-24 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

26. The following is a statement of reasons for the indication of allowable subject matter: no prior art of record teaches or fairly suggests the method of obtaining an indication of the intracranial pressure of a living body as set forth in claims 13-18; and no prior art of record teaches or fairly suggests the method of obtaining a measurement of the absolute pressure inside a cranium as set forth in claim 19-24.



**Conclusion**

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 3,610,233 teaches a piston and cylinder assembly for applying pressure. US 4,246,908 discloses an intracranial pressure transducer. US 5,291,899 discloses a method and device for measuring intracranial pressure. US 6,740,048 discloses a non-invasive method of determining diastolic intracranial pressure.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

30. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHARLES MARMOR  
PRIMARY EXAMINER